The opinion in support of the decision being entered today was <u>not</u> written for publication and is <u>not</u> binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte BILL H. McANALLEY

Application No. 10/001,439

HEARD: August 8, 2006



Before ADAMS, MILLS, and GREEN, <u>Administrative Patent Judges</u>.

MILLS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1, 8-17 and 19.

Claims 1 reads as follows:

1. A dietary supplement composition for a mammal, comprising a nutritionally effective amount of β -glucan, colostrums, lactoferrin, citrus pectin and a complex of essential saccharides.

The prior art references cited by the examiner are:

Donzis Paul Plaut 5,576,015 5,531,989 WO 97/05884

Nov. 19, 1996 Jul. 2, 1996 Feb. 20,1997

Grounds of Rejection

Claims 1, 8-17 and 19 stand rejected under 35 U.S.C. § 103(a) over Donzis, Paul and Plaut.

We affirm this rejection.

Claim Grouping

Appellants do not argue any claim separately with respect to the 35 U.S.C. § 103 rejection. Therefore, we select claim 1 as representative of the rejected claims. 37 C.F.R. § 41.37(c)(1)(vii) (Rev. 4, October 2005).

DISCUSSION

Obviousness

Claims 1, 8-17 and 19 stand rejected under 35 U.S.C. § 103(a) over Donzis, Paul and Plaut.

In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a <u>prima facie</u> case of obviousness. <u>See In re Rijckaert</u>, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). A <u>prima facie</u> case of obviousness is established when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art. <u>In re Bell</u>, 991 F.2d 781, 783, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993). An obviousness analysis requires

that the prior art both suggest the claimed subject matter and reveal a reasonable expectation of success to one reasonably skilled in the art. <u>In re Vaeck</u>, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991). With this as background, we analyze the prior art applied by the examiner in the rejection of the claims on appeal.

Although we agree that the prior art cited by the examiner supports a <u>prima facie</u> case of obviousness, our reasoning differs from that of the examiner and for this reason we designate our decision a new ground of rejection to provide appellant a full and fair opportunity to address any additional issues or concerns.

Paul describes an immunoglobulin and fiber-containing composition for human gastrointestinal health. Paul describes that immunoglobulins from bovine colostrum have been shown to be an effective treatment for diarrhea due to pathogenic organisms. Column 2, lines 21-29. Paul also indicates that immunoglobulin concentrates from milk contain active immunoglobulins that are capable of binding pathogenic organisms. Column 8, lines 10-16. Paul separates immunoglobulins from bovine milk and combines these purified immunoglobulins with lactoferrin, and dietary fibers such as inulin, guar gum and pectin^[1]. See e.g., column 3, line 58 – column 4, line 2 and formulation K, column 15. Paul acknowledges that soluble dietary fibers are found in many cereals. Column 6, lines 3-10. The composition of Paul may contain fructo-

¹ According to Paul (column 7, lines 13-15), "[r]ich sources of pectin include lemon and orange rinds. . ." Accordingly, Paul teaches citrus pectin.

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oligosaccharides, found in oats.² See, claim 1. The composition of Paul may be manufactured in powder form. Column 13, line 38. Paul additionally acknowledges that infants develop gastroenteritis about the time they are weaned from breast milk and placed on formula. Column 1, lines 51-62. Thus, Paul would reasonably appear to suggest a powdered composition comprising lactoferrin, guar gum, citrus pectin and immunoglobulins derived from colostrum that is appropriate for use in infants to prevent gastroenteritis.

Plaut similarly describes infant formulas comprising colostrum (pasteurized milk) and lactoferrin. Plaut, page 3. Plaut indicates that antibodies from colostrum are known to protect children from infection by several gastrointestinal pathogens. Page 2. Plaut suggests that colostrum may be used or antibodies can be purified from milk and combined with lactoferrin as used as a formula additive. Page 6, lines 15-18. In the regard, we note that Plaut discloses that the formula preferably includes colostrum. Plaut, page 5, lines 9-11. Finally, Donzis describes that glucan extracted from yeast cell walls is a potent stimulator of the immune system (Column 1, lines 20-21) and recommends that beta (1,3) glucans be incorporated as a nutritional supplement for a broad spectrum of animals and humans. Column 1, lines 52-67. Donzis indicates that beta glucan strongly enhances resistance to diseases, both viral and bacterial, and enhances growth rate, survival rate and feed efficiency. Column 3, lines 15-27.

² Beta glucan is a soluble fiber found in cereal grains such as oat, barley, and in yeast cell walls.

It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the colostrum of the infant formulas of Plaut comprising immunoalobulins, for the immunoalobulins derived from bovine colostrum of Paul into the composition of Paul, with the expectation that the colostrum incorporating natural immunoglobulins (Plaut) would function in a similar manner to the immunoglobulins derived from colostrum described in both Paut and Paul. It would have been further obvious to incorporate the yeast cell wall beta-glucan, an insoluble fiber, of the nutritional supplement of Donzis, into the immunoglobulin and fiber nutritional supplement of Paul with the expected benefit of stimulating the immune system, enhancement of resistance to diseases, both viral and bacterial, and enhancement of growth rate, survival rate and feed efficiency, and promotion of gastrointestinal health. Donzis specifically states that yeast extract beta glucan can be combined with conventional nutritional materials to create a more supportive environment within the body to assist the primary killing action of conventional agents and thereby enhance significantly growth and survival. Column 5, lines 50-60.

In view of the above, the references cited by the examiner support a <u>prima</u> facie case of obviousness.

In reply, appellant argues that the cited art fails to teach or suggest all the claim limitations and the cited references have been combined without proper motivation.

Brief, pages 6-7. In particular, appellant argues that the "Examiner has not presented"

any evidence on the record to support that the skilled artisan, reading Donzis [], Paul [] and Plaut [] would be motivated to combine the cited references" and that the combination is based on "impermissible hindsight". Brief, page 10. We are not persuaded by this argument. Each of the cited references describes components of nutritional supplements, such as infant formulas. Paul describes a nutritional supplement, primarily for gastrointestinal heath, for animals including infants, comprising immunogloblulins derived from colostrum, lactoferrin, citrus pectin and guar gum. Plaut describes an infant formula comprising colostrum and lactoferrin. In our opinion, a person of ordinary skill in the art would have found it obvious to substitute immunoglobulins obtained from colostrum as taught by Paul with the colostrum comprising immunoglobulins taught by Plaut. Where the prior art recognizes two components to be equivalent, an express suggestion to substitute one for another need not be present in order to render such substitution obvious. In re Fout, 675 F.2d 297, 301, 213 USPQ 532, 536 (CCPA 1982).

In addition, the desirability of adding a dietary fiber such as beta glucan to a nutritional supplement composition comprising various dietary fibers for the desired purpose of improving gastrointestinal and overall health is derived from the references themselves.

Appellant also points to the various deficiencies of each of the references individually, but fails to address the fair teachings of the cited references in combination. "[A]II of the disclosures in a reference ... 'must be evaluated for what they

fairly teach one of ordinary skill in the art." In re Inland Steel Co., 265 f.3d 1354, 1`361, 60 USPQ2d 1396, 1401 (Fed. Cir. 2001). More particularly, appellant argues Paul does not describe beta glucan and colostrums, Plaut does not describe beta glucan, citrus pectin and essential polysaccharides and Donzis does not describe each of the claimed ingredients. Brief, pages 6-7. However, the rejection is based on a combination of references. "Non-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references." In re Merck & Co., Inc., 800 F.2d 1091, 1097, 231 USPQ 375, 380 (Fed. Cir. 1986). The test of obviousness is "whether the teachings of the prior art, taken as a whole, would have made obvious the claimed invention." In re Gorman, 933 F.2d 982, 986, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991).

We find the examiner has provided sufficient evidence to support a <u>prima facie</u> case of obviousness which remains unrebutted by appellants.

CONCLUSION

The rejection of claims 1, 8-17 and 19 under 35 U.S.C. § 103(a) over Donzis, Paul and Plaut is affirmed. As our analysis varies from that of the examiner we designate our decision in this appeal as a new ground of rejection.

This decision contains a new ground of rejection pursuant to 37 CFR § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)). 37 CFR § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review."

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37 C.F.R. § 41.50(b) also provides that the appellant, <u>WITHIN TWO MONTHS</u>

<u>FROM THE DATE OF THE DECISION</u>, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

- (1) Reopen prosecution. Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the proceeding will be remanded to the examiner. . . .
- (2) Request rehearing. Request that the proceeding be reheard under § 41.52 by the Board upon the same record. . . .

AFFIRMED, 37 C.F.R §41.50(b)

Donald E. Adams

Administrative Patent Judge

Demetra J. Mills

Administrative Patent Judge

APPEALS AND

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) INTERFERENCES

Lora M. Green

Administrative Patent Judge

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